NMPF's Regulatory Register

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PRELIMINARY RESULTS OF 2003 NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

The National Conference on Interstate Milk Shipments (NCIMS) met in Seattle, WA from April 26 – May 1, 2003 to address the 150 proposals submitted to revise the *Pasteurized Milk Ordinance* (PMO) and its related documents. The National Milk Producers Federation (NMPF) staff attended the Conference to advocate positions of interest to dairy cooperatives and their producer members. Many NMPF members also attended and played key roles in the deliberations of the Conference.

Overall, the 2003 Conference was very positive for all parties and issues were discussed with a high degree of professionalism. State delegates, the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the dairy industry participants all came to the Conference to talk through the topics at hand and make certain the cooperative aspects of the NCIMS program remained strong and viable.

Proposals of significance to dairy cooperatives and producers are detailed below. All proposals relate to the 2001 *Pasteurized Milk Ordinance*, the 1995 *Dry Milk Ordinance*, the 2001 *Methods of Making Sanitation Ratings of Milk Shippers*, the 1995 *Evaluation of Milk Laboratories*, and the 2001 *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program for Certification of Interstate Milk Shippers* (Procedures) documents.

The following proposals were **passed** by the delegates and will be incorporated into the appropriate documents:

Raw Milk Issues:

- Allow for automatic milk systems on farms. NCIMS has been conducting a study of these systems, many of which are currently in use. This proposal provides specifics for how to install and operate these systems to be in compliance with the PMO.

- Provide guidance for implementing monetary penalties in lieu of degrading milk when non-safety items are the result of the degrade. This proposal will provide States some flexibility on how to handle appropriate regulatory actions. This will be particularly useful in those areas where the market for manufactured grade milk is shrinking.

- Allow for the use of cooling ponds. The PMO specifically prohibited any standing water in the cowyard, but southern regions need to allow for a pond to enable cows to maintain their comfort during particularly hot times of the year. This proposal allows for cooling ponds and requires that the State be involved in ensuring they do not represent a safety hazard to the milk supply.

- NMPF proposal to allow for top filling of bulk tanks using flexible hoses. Previously, flexible hoses were only allowed for

bottom filling. This proposal will allow for additional means of compliance with PMO requirements at the farm.

- Proposal to define the drug residue avoidance language in Appendix N of the PMO. Previously, this language was generic and did not provide enough guidance for some regulatory agencies when producers were found to be violative for animal drug residues.

- Approve the Charm SL-6 Beta-lactam test and the IDEXX new SNAP Beta-lactam test to detect animal drug residues in milk. Both of these tests are new versions and have been approved. Use of these over some of the older tests should make the incidence of positive results below the safe/ tolerance level decrease.

- Add wording to PMO that requires averaging of somatic cell counts, bacterial counts, and temperature results.

- Allow bulk milk tanks to be sampled using a sample septum and sterile needle. This proposal will allow for samples to be taken without contaminating them, as can occasionally happen with the current sampling methods.

- Allow for in-line sampling systems. These systems will provide for an additional means to obtain a representative sample.

- Allow split samples for laboratories approved for visually reading test results to be sent to certified labs at the same time as regular split samples. This will eliminate the special samples that are sent for visual lab tests.

- Allow milk from species other than cows, goats, and sheep to be used in Grade "A" products. Some States are seeing a desire by farmers of water buffalo and other species to manufacture Grade "A" products.

Milk Hauling Issues:

- Require cleaning and sanitation stations to be permitted. This proposal merely clarifies some language and does not require these stations at non-Grade "A" facilities to become Grade "A".

- Proposal to clarify hauling and sampling language. The 2001 NCIMS implemented a number of requirements for milk haulers and samplers. This proposal clarifies some of those requirements, as a result of work with the program over the past two years.

Pasteurized Milk Issues:

- Approve the current HACCP pilot program as an official option under the NCIMS Program. This program has been pilot tested for 4 years and the delegates have now made it an approved option for any plant wishing to participate.

- Protocols for allowing plants to operate beyond the current 24 hours prior to cleaning and sanitizing were defined. While extended runs were previously permitted, they were evaluated on a case-by-case basis. This proposal provides for specific protocol that must be met and should allow more uniformity in how extended runs are reviewed.

- Allow continuously operated evaporators to run for 44 hours without having to clean and sanitize. This proposal does not require these evaporators to provide an extended run protocol and recognizes that they have been used over extended periods already.

- A number of proposals that will provide flexibility to aseptic, ultra-high temperature, and ultra-pasteurized product equipment. Previously, the PMO only allowed for these systems if very specific criteria were met.

A number of proposals were passed that will allow for variations to these systems and provide the necessary flexibility to processing facilities.

- Extend the time for a mandatory regulatory agency sealing of timing pumps after industry has sealed them to 10 days. The previous requirement was for regulatory agencies to re-seal within 3 days and could not always be guaranteed. This proposal will provide for some welcome relief in those instances where industry must seal timing pumps but regulatory agencies cannot visit the plant within 3 days.

- Allow for treatments other than pasteurization for water that is used to rinse equipment in dairy plants. This proposal is the result of a two-year study on what requirements need to be met for water that is used to rinse pasteurization equipment. Options for using treatments other than pasteurizing the water are provided, as long as they are acceptable to the Regulatory Agencies.

- Study the appropriate levels of vitamins in the PMO to make it consistent with the CFR. FDA is examining the addition of vitamins to higher fat products to ensure no health hazards due to over fortification occur.

- Clarify the equipment language for UF and RO systems. This proposal adds language to the PMO to allow for those UF and RO systems that are already in use across the US and provides guidance for new systems.

- Scientific Review Committee of NCIMS will review the scientific justification for keeping heated dairy products above 145°F.

- Exempt ultra-pasteurized, extended shelf-life, and condensed products from phosphatase testing requirements. While it was understood that no testing was required, this proposal better defines it in the PMO.

- Allow for electronic pipettors to be used in NCIMS approve laboratories.

- Add definitions for Aseptic Processing, Ultra-Pasteurization, and Sanitization to the PMO. These definitions were previously removed and have, apparently, caused some confusion as to how to define these terms.

- Add definition for Industry Plant Sampler to the PMO. This definition was not in the PMO and will provide some clarification as to the duties and training requirements for this group of individuals.

Miscellaneous Issues:

- FDA Memoranda of Interpretation (M-a's) and Memoranda of Information (M-I's) were also added to the PMO. These were included as a result of an agreement between the NCIMS Executive Board, NCIMS Liaison Committee, and FDA. The memos address a variety of areas of the PMO, but are not new requirements. All of the requirements have previously been in force as existing memoranda.

- Update the *Evaluation of Milk Laboratories* document on a regular basis. Currently, the document is not kept as up-to-date as the other NCIMS documents. This proposal will require an update every two years (after every Conference).

- Allow for a pilot program that will allow States to contract with a third party to conduct NCIMS work for foreign facilities. This proposal is intended to require foreign firms to meet the same requirements as US firms before Grade "A" products can be shipped into the US. After a State has

implemented this program, they should be better able to keep illegally imported products from entering the US. NMPF will work with States to identify the illegally imported products so that States can take immediate action against these products.

- Change the state program evaluations from biennial to triennial. This proposal will allow FDA to conduct more complete evaluations of state programs and assist States in following NCIMS requirements.

The following proposals were considered potentially onerous or unnecessary by NMPF and were **not passed** by the Conference delegates. Consequently, they will not be incorporated into the new documents:

- Lower the regulatory limit for somatic cells in the PMO to 400,000 cells/ml over a period of time. The current regulatory limit of 750,000 cells/ml will remain in place.

- Introduce detailed requirements for milking time and non-milking time inspections at dairy farms.

- Require farm water samples to be taken every year. The current requirement of once every 3 years will remain.

- Require additional information on farm bulk weight tickets. This proposal created a lengthy list of items that would have been included on weight tickets. If the information were not included, a debit would have resulted.

- Require the last product hauled in a tanker to be listed on the wash tag.

- Define the sampling frequency for seasonally produced dairy products.

- Define sampling requirements for cold separated products.

- Require shielding and drainable seals around ingredient tank agitators.

- Add onerous and detailed procedures that would be required for any plant that wished to operate extended runs. While a protocol was passed with a different proposal, this proposal, which contained a number of unnecessarily specific items that could be untenable for industry, was defeated.

- Add a definition that would include any product with more than 50% dairy ingredients as Grade “A” products.

- Remove the requirement for labeling reconstituted and recombined dairy products as reconstituted and recombined.

- Bring ice cream and cheese products under the NCIMS Program.

Elections to the Executive Board also occurred at the Conference. Marlena Bordson, Illinois Department of Public Health was elected as Chairwoman and John O’Connor, Garelick Farms was elected as Vice Chairman. In addition, the Western Region representatives on the Executive Board will consist of Darwin Kurtenbach, SD; Jodeen Meenderink, Dean Foods; Eric Paulson, OR; and Duane Spomer, USDA. The vacant Board seat in the Central Region will be filled by Sue Esser, MI. The vacant Board seat in the Eastern Region will be filled by John Beers, VA. A complete list of the Executive Board is given below.

The changes to Conference documents will become effective within 1 year publication of the PMO in electronic form. This will occur some time after the meeting between the Executive Board and FDA to discuss the proposals with which FDA does and does not concur. This meeting is usually scheduled for late August or early September.

NMPF Staff would like to thank all members who attended the Conference and assisted in the deliberations of the proposals. Your assistance in advocating the industry interests was vital to the success of the Conference.

If you have any questions about NCIMS or the disposition of any of the proposals, please contact Rob Byrne at the NMPF offices.

Executive Board

Marlena Bordson	Chair	Springfield, IL
John O'Connor	Vice Chair	Lynn, MA

Region I - Eastern States, Terms Expire 2005

Byron Moyer	State Rating	Montpelier, VT
John Beers	State Enforcement	Richmond, VA
Kevin Charles	State Enf./Rating/Health	Dover, DE
John O'Connor	Industry	Lynn, MA
Faye Feldstein	FDA	College Park, MD

Region II - Central States, Terms Expire 2007

John Sanford	State Rating	Nashville, TN
Marlena Bordson	State Enforcement	Springfield, IL
John Bruhn	Academia	Davis, CA
Sue Esser	State Enf./Rating/Health	Lansing, MI
Arlen Schwinke	Industry	Morrison, MO
Frank Barcellos	Laboratory	Tulsa, OK

Region III - Western States, Terms Expire - 2009

Darwin Kurtenbach	State Rating	Pierre, SD
Eric Paulson	State Enforcement	Salem, OR
Kyle Stephens	State Enf./Rating/Health	Salt Lake City, UT
Jodeen Meenderink	Industry	Salt Lake City, UT
Duane Spomer	USDA	Washington, DC

Ex Officio

Sue Esser	Council I	Lansing, MI
John Beers	Council II	Richmond, VA
Kyle Stephens	Council III	Salt Lake City, UT
Dan Borer	Past Chairman	Lincoln, NE
Vacant	Program Chair	
Rob Byrne	NMPF Representative	Arlington, VA
Cary Frye	IDFA Representative	Washington, DC
Vacant	Consumer Representative	
Leon Townsend	Executive Secretary	Frankfort, KY

The following is a list of the proposals and the final action by the voting delegates.

Proposal	Result	Proposal	Result	Proposal	Result	Proposal	Result
101	P	139	NA	205	NA	243	NA
102	P	140	NA	206	P	244	NA
103	P	141	P	207	P	245	NA
104	NA	142	P	208	P	246	NA
105	NA	143	NA	209	NA	247	NA
106	NA	144	NA	210	NA	248	P
107	P	145	P	211	NA	249	NA
108	P	146	Table	212	NA	250	WD
109	P	147	P	213	NA	251	NA
110	NA	148	P	214	P	252	WD
111	NA	149	NA	215	P	253	NA
112	NA	150	P	216	NA	254	P
113	P	151	P	217	P	255	P
114	P	152	P	218	P	256	P
115	NA	153	P	219	NA	257	P
116	P	154	P	220	P	258	P
117	P	155	P	221	NA	259	P
118	P	156	P	222	NA	260	NA
119	P	157	NA	223	NA	301	P
120	P	158	P	224	NA	302	P
121	P	159	NA	225	NA	303	P
122	P	160	NA	226	NA	304	NA
123	NA	161	P	227	P	305	P
124	P	162	P	228	P	306	P
125	NA	163	P	229	NA	307	NA
126	P	164	P	230	NA	308	NA
127	P	165	NA	231	NA	309	NA
128	P	166	P	232	NA	310	NA
129	P	167	P	233	P	311	NA
130	P	168	P	234	P	312	NA
131	P	169	P	235	WD	313	NA
132	P	170	P	236	NA	314	NA
133	P	171	NA	237	P	315	P
134	WD	172	P	238	NA	316	P
135	P	201	NA	239	P	317	NA
136	P	202	NA	240	P	318	NA
137	NA	203	NA	241	NA		
138	NA	204	P	242	NA		

P = Passed, either as submitted or with amendments.
NA = No Action (i.e., failed).
WD = Withdrawn by submitter.
Table = To be considered at a later time.